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REMARKS

Applicant thanks Examiner Dickens for her attention to the present application.

All the previously pending claims, Claims 1-33 were rejected under 35 U.S.C. §102(b) as being anticipated by Krivitski. Examiner Dickens relied upon Krivitski ('989) to disclose introducing a discrete volume change to the initial flow rate, sensing within the conduit a corresponding resulting change and determining the initial flow rate in response to the introduced volume change and the sensed resulting change.

Applicant respectfully submits the term "volume change" has a specific meaning as set forth in the present application. Specifically, "volume change" is directed to a known volume over a *known time*, such as a known flow rate wherein either of the known volume or known time can be acquired by measurement. (Page 7-9)

In contrast to the present claims, Krivitski '989, discloses only the volume of introduced indicator is known, and employed in conjunction with a resulting dilution curve to determine a flow rate. Specifically, Krivitski '989 discloses:

$$Q = V/S;$$

$$Q_{\text{shunt}} = V_{\text{ven}}/S_{\text{art}} - Q_{\text{dial}};$$

$$Q_{\text{shunt}} = Q_{\text{dial}} (V_{\text{ven}}/V_{\text{cal}} \times S_{\text{cal}}/S_{\text{art}} - 1);$$

$$Q_{\text{shunt}} = (V_{\text{ven}}/S_{\text{art}} \times V_{\text{cal}}/S_{\text{cal}});$$

$$Q_{\text{shunt}} = Q_{\text{dial}} (S_{\text{ven}}/S_{\text{art}} - 1);$$

where Q is a rate of blood flow;

V is an amount of injected indicator;

S is an area under a dilution curve;

Q_{shunt} is a rate of blood flow through the arterio-venous shunt;

V_{ven} is a volume of indicator introduced into a venous line;

S_{art} is an area under a dilution curve in an arterial line;

Q_{dial} is a dialyzer rate of blood flow;

V_{cal} is a known quantity of indicator in a calibration injection;


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S_{cal} is an area under a dilution curve corresponding to V_{cal} ; and
 S_{ven} is an area under a dilution curve in an arterial line.

It is important to note that none of these relationships disclose or suggest a known time in conjunction with a known volume. The present claims recite reliance upon a *known volume over a known time*, and thus cannot be anticipated by Krivitski '989.

Therefore, applicant respectfully submits all the pending claims, Claims 1-38 are in condition for allowance such action is earnestly solicited. If, however, the examiner feels that any further issues remain she is cordially invited to contact the undersigned so that such matters may be promptly resolved.

Respectfully submitted,


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VERSION WITH MARKINGS SHOWING CHANGES MADE

conduit, comprising:

rate;

(c) determining the initial flow rate in response to the introduced known volume, the

known time [change] and the sensed resulting change.

from the conduit.

sensor and a liquid characteristic sensor.

downstream location to the introduced volume [change].

the conduit.

known time [change] through a catheter in the conduit.

change in one of a liquid characteristic and a flow characteristic.

sensing a corresponding resulting change proportional to the flow in the conduit.

"introduce", as opposed
 by Webster's II
 New Riverside University
 Dictionary, is "to inject or
 insert" or "to bring or
 put in something diff.
 ADD. Thus it is not
 clear how the stop
 "or introducing" includes
 "withdrawing".
 "withdrawing" is "total
 back or away" "remove".

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9. The method of Claim 1, wherein sensing a corresponding resulting change includes sensing one of a velocity, pressure and flow rate of the flow in the conduit.

10. The method of Claim 1, wherein sensing a corresponding resulting change includes sensing a dilution indicator.

11. (Once Amended) A method for determining an initial flow rate in a conduit, comprising:

(a) locating a catheter in the conduit;

(b) introducing a known [volume change] flow rate to the initial flow rate through the catheter; and

(c) determining the initial flow rate in response to the introduced known [volume change] flow rate and a resulting change in the initial flow rate.

12. (Once Amended) The method of Claim 11, wherein introducing a known [volume change] flow rate includes introducing a discrete volume change.

13. (Once Amended) The method of Claim 11, wherein introducing a known [volume change] flow rate includes injecting or withdrawing [the] a discrete volume from the conduit.

14. The method of Claim 11, further comprising employing one of a flow characteristic sensor and a liquid characteristic sensor.

15. (Once Amended) The method of Claim 11, wherein sensing the corresponding resulting change includes sensing at an upstream location to the introduced known [volume change] flow rate and a downstream location to the introduced known [volume change] flow rate.

16. The method of Claim 11, wherein sensing a corresponding resulting change includes sensing with a sensor located at one of in the conduit, on the conduit or spaced from an exterior of the conduit.

17. (Once Amended) The method of Claim 11, further comprising sensing a resulting change after introducing the known [volume change] flow rate.

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18. (Once Amended) The method of Claim 17, wherein sensing the resulting change includes sensing a change corresponding to the introduced known [volume change] flow rate in one of a liquid characteristic and a flow characteristic.

19. The method of Claim 17, further comprising sensing a resulting change as proportional to the flow in the conduit.

20. (Once Amended) A method for determining an initial flow rate in a conduit, comprising:

(a) introducing a discrete known volume over a known time [change] to the initial flow in the conduit to produce a resulting change in the initial flow; and

(b) determining the initial flow rate in response to the introduced discrete known volume, the known time [change] and the resulting change.

21. The method of Claim 20, further comprising employing a sensor to sense the resulting change in the flow.

22. (Once Amended) An apparatus for determining an initial flow rate in a conduit, comprising:

(a) means for introducing a discrete known volume over a known time [change] to the initial flow;

(b) a sensor for measuring a corresponding change resulting from the introduced discrete known volume over the known time [change]; and

(c) a controller connected to the sensor, the controller configured to determine the initial flow rate in a response to the known volume, the known time [change] and the corresponding change.

23. The apparatus of Claim 22, further comprising a catheter having an introduction port.

24. The apparatus of Claim 23, wherein the sensor is connected to the catheter.

25. (Once Amended) An apparatus for determining an initial flow rate in a conduit, comprising:

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- (a) a known flow rate [volume change] introducer selected to effect a discrete known flow rate [volume change] to produce a resulting change in the initial flow in the conduit;
- (b) a sensor for measuring the resulting change; and
- (c) a controller connected to the sensor, the controller configured to determine the initial flow rate in a response to the known flow rate [volume change] and the resulting change measured by the sensor.

26. (Once Amended) A method for determining an initial blood flow rate in a conduit, comprising:

- (a) introducing a known flow rate [volume] of an indicator into the conduit to create a discrete volume change in the initial flow and a liquid characteristic change in the conduit;
- (b) optically sensing the liquid characteristic change in the conduit with a sensor located external to the conduit; and
- (c) determining the initial blood flow rate in the conduit in response to the introduced known flow rate [volume] of indicator and the sensed liquid characteristic change.

27. (Once Amended) The method of Claim 26, wherein introducing the known flow rate [volume] of the indicator includes introducing a change in blood hematocrit in the conduit.

28. (Once Amended) The method of Claim 26, wherein introducing the known flow rate [volume] of the indicator includes introducing a solution including at least one of saline and glucose into the conduit.

29. The method of Claim 28 further comprising introducing an isotonic solution into the conduit.

30. The method of Claim 26, wherein optically sensing the liquid characteristic change includes obtaining a value proportional to the liquid characteristic change.

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31. (Once Amended) The method of Claim 26, wherein introducing the volume of the indicator into the conduit includes introducing the known flow rate [volume] of indicator upstream of an area sensed by the optical sensor.

32. The method of Claim 26, wherein the liquid characteristic is blood hematocrit.

33. The method of Claim 26, wherein optically sensing the liquid characteristic change includes obtaining a value proportional to blood hematocrit in the conduit.

Please add the following new claims:

34. (New) The method of Claim 1, further comprising measuring to identify one of the known volume and the known time.

35. (New) The method of Claim 11, further comprising determining the known flow rate by measuring.

36. (New) The method of Claim 20, wherein one of the known volume and the known time is determined by measuring.

37. (New) A method for determining an initial blood flow rate in a conduit, comprising:

(a) determining the initial blood flow rate Q , corresponding to at least one of the following and an analogous relationships:

$$Q = \frac{Q_i}{\left(\frac{\Delta Q_d}{Q_d} - \frac{\Delta Q_u}{Q_u} \right)}; Q = \frac{Q_i}{(C_{bd} - C_{bu})}; Q = \frac{Q_i}{\left(\frac{\Delta V_d}{V_d} - \frac{\Delta V_u}{V_u} \right)}; Q = \frac{Q_i}{\left(\frac{\Delta hu}{h_{ui}} - \frac{\Delta hd}{h_{di}} \right)};$$

$$Q = \frac{Q_i}{\left(\frac{\Delta Pd}{Pd - P_{ven}} - \frac{\Delta Pu}{Pu - P_{art}} \right)}$$

where Q_i is the introduced volume during the introduced time;

$$\Delta Q_d = Q_{di} - Q_d;$$

$$\Delta Q_u = Q_{ui} - Q_u;$$

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Q_d is the flow rate downstream of an introduction point of Q_i ;

Q_u is the flow rate upstream of an introduction point of Q_i ;

C_{bd} is the relative change in a flow corresponding parameter from an upstream volume injection;

C_{bu} is the relative change in a flow corresponding parameter from a downstream volume injection;

ΔV_u is a change corresponding to an upstream blood velocity;

ΔV_d is a change corresponding to a downstream blood velocity;

V_u is an upstream blood velocity;

V_d is a downstream blood velocity;

h_u is a concentration of indicator measured at an upstream sensor;

h_d is a concentration of indicator measured at a downstream sensor;

$\Delta h_u = h_{ui} - h_u$; and

$\Delta h_d = h_{di} - h_d$.

38. (New) A method for determining an initial blood flow rate in a conduit, comprising:

(a) determining the initial blood flow rate Q , corresponding to an introduced flow rate to the initial flow rate.

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